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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,568	12/14/2001	Michael B. Zemel	31894-192402	9941
26694	7590	07/10/2008		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER FISHER, ABIGAIL L	
			ART UNIT	PAPER NUMBER
			1616	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/017,568

**Applicant(s)**

ZEMEL ET AL.

**Examiner**

ABIGAIL FISHER

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-27, 29 and 35-68 is/are pending in the application.
- 4a) Of the above claim(s) 22, 25-27, 29, 42-49, 51-54, 59-62 and 64-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 23-24, 35-41, 50, 55-58 and 63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/13/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Amendments/Remarks filed on February 13 2008 is acknowledged. Claims 1-20, 28, 30-34 and 69-77 were/stand cancelled. Claim 38 was amended. Claims 21-27, 29, 35-68 are pending. Claims 22, 25-27, 29, 42-49, 51-54, 59-62 and 64-68 are withdrawn as being directed to a non-elected invention. Claims 21, 23-24, 35-41, 50, 55-58 and 63 are directed to the elected invention.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on February 13 2008 was considered by the examiner.

### ***Examiner Notes***

Applicant is reminded that pursuant to MPEP 714, 27 CFR 1.121 requires that all amendments to the claims must contain a claim listing indicating the status of each claim. In the instant claim set, claim 38 was amended as demonstrated by the underlined text in the claim as well as the applicant as indicated in their response that this claim was amended. However, the claim status lists the claim as previously presented. The examiner believes that this is a typo and should state currently amended.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 21, 23, 35-40, 50, 55-58 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The appearance of mere indistinct words (here the word "antagonist" and "analog") in a specification or a claim, even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material does, rather than what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

The specification sets forth administration of a 1,25-dihydroxyvitamin D receptor antagonist. Nowhere, however, does it specify which particular compounds have the desired characteristic of inhibiting 1,25-(OH)<sub>2</sub>-D, other than 1-β, 25-dihydroxyvitamin D and its corresponding homologs or isomers and calcium.

Accordingly, the requisite correlation between structure and function as set forth in Rochester is not provided here; at best all that can be inferred from the instant specification is that 1-β, 25-dihydroxyvitamin D and the corresponding homologs or isomers, antagonize the 1,25-(OH)<sub>2</sub>-D receptor.

The claims are also directed to encompass analogs, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these analogs meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**Claims 21, 23, 38-39, and 57 are rejected under 35 U.S.C. 102(a) as being anticipated by McCarthy (Remedy, March/April 2000).**

The instant application claims a method of regulating body weight comprising administering an antagonist of calcitrophic hormone (1,25-(OH)<sub>2</sub>-D) activity in an amount effective to block calcitrophic hormone activity in adipocytes of said individual, said antagonist inducing weight loss, attenuating, controlling, and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue.

McCarthy discloses the results of three different studies. It was found that consuming more calcium decreases production of a hormone called 1,25 dihydroxyvitamin D which stimulates fat production ( third column, 4<sup>th</sup> paragraph). Administration of calcium results in a drop of 1,25-dihydroxyvitamin D (column 4, first paragraph). It is taught by McCarthy that administration of foods containing calcium resulted in a loss of an average of 11 pounds in one study (third column, third paragraph).

#### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 21, 23, 28, 38-40, 50 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al. (Clinical Orthopaedics and Related Research, 1977).**

#### **Applicant Claims**

Applicant claims a method of regulating body weight comprising administering an antagonist of calcitrophic hormone (1,25-(OH)<sub>2</sub>-D) activity in an amount effective to block calcitrophic hormone activity in adipocytes of said individual, said antagonist

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inducing weight loss, attenuating, controlling, and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue.

**Determination of the Scope and Content of the Prior Art  
(MPEP §2141.01)**

Larsson et al. disclose the administration of 1,25-DHCC (1,25-dihydroxycholecalciferol) to animals. Animals treated with 120-60 ng of 1,25-DHCC had an average loss of body weight of 40% while those given 30 ng of 1,25-DHCC exhibited body weight reductions which averaged 21% (page 230, right column, second paragraph). It is disclosed that the 1,25-DHCC is administered in 95% ethanol (page 229, left column, materials and methods), therefore it is in liquid form.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Larsson et al. does not specify that 1,25-DHCC can be administered in a method of regulating body weight.

***Finding of Prima Facie Obviousness Rational and Motivation*  
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to administer 1,25-DHCC in a method of regulating body weight. One of ordinary skill in the art would have been motivated to utilize 1,25-DHCC in this type of method because Larsson et al. teach that administration of this compound results in a loss of body weight.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Larsson et al. does not specify that 1,25-DHCC is an antagonist. However, Applicant has claimed that the antagonist is a chemical compound that binds to 1,25-(OH)<sub>2</sub> D receptor. Furthermore instant claim 40 indicates that the antagonist is an isomer of 1,25-(OH)<sub>2</sub>. Therefore, based on these definitions, 1,25-DHCC is necessarily an antagonist.

**Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al. in view of Jequier (Am. J. Clin. Nutr. 1987).**

**Applicant Claims**

Applicant claims that the individual has Grade I, Grade II and Grade III obesity (separately claimed).

**Determination of the Scope and Content of the Prior Art  
(MPEP §2141.01)**

The teachings of Larsson et al. are set forth above. Specifically, Larsson et al. teach that administration with 120-60 ng of 1,25-DHCC had an average loss of body weight of 40% while those given 30 ng of 1,25-DHCC exhibited body weight reductions which averaged 21% in animals.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Larsson et al. does not specify administration to individuals with Grade I, Grade II, or Grade III obesity. However, this deficiency is cured by Jequier.

Jequier discloses that desirable range of a BMI for women and men is between 20-25. Grade 1 obesity corresponds to a BMI of 25-29.99. Grade II of 30-40 and Grade

III greater than 40. The health risks associated with obesity include mortality, dyslipidemia, hypertension, or diabetes (page 1035, left column, 2nd and 3rd paragraphs).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Larsson et al. and Jequier and administer 1,25-DHCC to individuals with Grade I, Grade II, and Grade III obesity. One of ordinary skill in the art would have been motivated to administer 1,25-DHCC to these types of individuals because they are great risk for developing diseases and even death as taught by Jequier. Therefore, one of ordinary skill in the art would have been motivated to administer a compound that is known to decrease body weight in order to help these individuals lessen their risk of developing the diseases associated with obesity.

**Claims 24, 40-41, 50, 55-56, 58 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy (Remedy, March/April 2000) in view of Norman et al. (JBC, 1993, cited on PTO Form 1449).**

**Applicant Claims**

Applicant claims a method of regulating body weight comprising administering an antagonist of calcitrophic hormone (1,25-(OH)<sub>2</sub>-D) activity in an amount effective to block calcitrophic hormone activity in adipocytes of said individual, said antagonist inducing weight loss, attenuating, controlling, and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue.

**Determination of the Scope and Content of the Prior Art  
(MPEP §2141.01)**

McCarthy discloses the results of three different studies. It was found that consuming more calcium decreases production of a hormone called 1,25 dihydroxyvitamin D which stimulates fat production ( third column, 4<sup>th</sup> paragraph). It is taught by McCarthy that administration of foods containing calcium resulted in a loss of an average of 11 pounds in one study (third column, third paragraph). Administration of calcium results in a drop of 1,25-dihydroxyvitamin D (column 4, first paragraph).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

McCarthy does not disclose the administration of  $1\beta,25-(OH)_2 D_3$  in a method of regulating body weight or that the activity that is blocked is increasing intracellular calcium concentrations. However, this deficiency is cured by Norman et al.

Norman et al. teach that  $1\alpha,25-(OH)_2 D_3$  is an agonist of the hormonally active form of vitamin  $D_3$  (page 20028, right column, second paragraph and page 20025, right column, first paragraph).  $1\alpha,25-(OH)_2 D_3$  results in the stimulation of  $Ca^{2+}$  (page 20025, right column, first paragraph).  $1\beta,25-(OH)_2 D_3$  however is an antagonist of  $1\alpha,25-(OH)_2 D_3$  in terms of the  $1\alpha,25-(OH)_2 D_3$  mediated transcalcachia and  $Ca^{2+}$  uptake (abstract and figures 2 and 3).

**Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to combine the teachings of McCarthy and Norman et al. and utilize  $1\beta,25-(OH)_2 D_3$  in a method of

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regulating body weight. One of ordinary skill in the art would have been motivated to utilize  $1\beta,25-(\text{OH})_2 \text{D}_3$  in this method because McCarthy teaches that 1,25-dihydroxy vitamin  $\text{D}_3$  stimulates fat production and Norman et al. teach that  $1\beta,25-(\text{OH})_2 \text{D}_3$  is an antagonist of 1,25-dihydroxy vitamin  $\text{D}_3$ . Therefore, one of ordinary skill in the art would have a reasonable expectation that the antagonist would inhibit fat production as it is taught as an antagonist of the fat stimulating hormone.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

**Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy in view of Jequier.**

#### **Applicant Claims**

Applicant claims that the individual has Grade I, Grade II and Grade III obesity (separately claimed).

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

The teachings of McCarthy are set forth above. Specifically, McCarthy teach that studies indicate that administration of calcium decreases production of 1,25-dihydroxyvitamin  $\text{D}_3$  a hormone that stimulates fat production.

#### **Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)**

McCarthy does not specify administering calcium to individuals with Grade I, Grade II or Grade III obesity. However, this deficiency is cured by Jequier.

Jequier discloses that desirable range of a BMI for women and men is between 20-25. Grade 1 obesity corresponds to a BMI of 25-29.99. Grade II of 30-40 and Grade III greater than 40. The health risks associated with obesity include mortality, dyslipidemia, hypertension, or diabetes (page 1035, left column, 2nd and 3rd paragraphs).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of McCarthy and Jequier and administer 1,25-DHCC to individuals with Grade I, Grade II, and Grade III obesity. One of ordinary skill in the art would have been motivated to administer 1,25-DHCC to these types of individuals because they are great risk for developing diseases and even death as taught by Jequier. Therefore, one of ordinary skill in the art would have been motivated to administer a compound that is known to decrease body weight in order to help these individuals lessen their risk of developing the diseases associated with obesity.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher  
Examiner  
Art Unit 1616

AF

/Mina Haghighatian/  
Primary Examiner, Art Unit 1616